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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,758	10/14/2005	M. Dean Savage	F-PRCB-05	1329

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EXAMINER

MARTIN, PAUL C

ART UNIT PAPER NUMBER

1657

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/517,758

Applicant(s)

SAVAGE, M. DEAN

Examiner

Paul C. Martin

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-24 are pending in this application and were examined on their merits.

Specification

The objection to the Specification has been withdrawn due to the Applicant's amendments to the Specification filed 09/20/06.

Claim Objections

The objection to Claim 11 has been withdrawn due to the Applicant's amendments to the Claims filed 09/20/06. The amendment of Claims 12 and 13 to correct a similar problem is noted.

Claim Rejections - 35 USC § 103

The rejection of Claims 1-22 under 35 USC § 103 (a) as being unpatentable over Nikiforov (US 6,472,141 B2) as evidenced by Cox *et al.* (US 5,034,189)★ has been withdrawn because the Applicant's arguments regarding the differences in assaying fluorescence polarization and fluorescence quenching were found to be persuasive.

Double Patenting

The provisional rejection of Claim 1-13 under 35 USC § 101 as claiming the same invention as that of Claims 1-11 of co-pending Application No. 10/865893 has been withdrawn due to the Applicant's withdrawal of Claim 1-11 by Election.

Claims 14, 22, 23 and 24 remain provisionally rejected under 35 USC § 101 as claiming the same invention as that of Claims 28, 37, 63 and 74 of co-pending Application No. 10/865893.

Claims 15-21 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29, 32, 34, 35, 37 and 38 of copending Application No. 10/865,893. Although the conflicting claims are not identical, they are not patentably distinct from each other; the claims of '758 'anticipate' Instant claims 15-21 due to the fact that they teach every limitation of Instant claims 15-21.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 19-21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to a lack of antecedent basis has been withdrawn due to the Applicant's amendments to the claims.

Claims 1-14, 19 and 22-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydrolases such as kinases, phosphatases and proteases, does not reasonably provide enablement for all possible enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth in the Office Action mailed 06/29/06.

The Applicant argues the method is applicable for many other enzymes beyond those hydrolases specifically disclosed in the instant specification (kinases, phosphatases and proteases) because one of skill in the art would know that enzymes function in the same general way in that they modify a substrate to produce a product and that the particular substrate requirements for a specific enzyme class are readily available or determinable (Remarks, Pg. 7, Paragraph 1).

Response to Arguments

The Applicant's arguments have been considered but are not found to be persuasive for the following reasons. The Applicant's assertion that the method can assay the activity of an enzyme of choice, does not provide support in the form of specific guidance or direction as to what enzymes will work (or not work) in the claimed invention. It is unreasonable to assume that the invention will work for any enzyme under the sun, without any working examples, data or reaction parameters indicating that it will, in fact, work as claimed. While one of ordinary skill in the art may be aware of the substrate requirements of a specific enzyme class, this knowledge will not impart the ability to select any particular enzyme and substrate and immediately make the claimed invention without undue experimentation to ascertain inoperable embodiments and to determine the reaction parameters, such as optimal pH, temperature, concentrations and optimizing the assay based upon the enzyme type.

An assay based upon an enzyme which cleaves a substrate (such as a protease) will necessarily vary from an assay based upon the joining of substrates (such as a ligase) and so forth.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 8, 9, 11-13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Nikiforov (US 6,699,655 B2) as evidenced by Cox *et al.* (US 5,034,189)★).

Claims 1, 2, 4-6, 8, 9, 11-13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Nikiforov (US 6,472,141) as evidenced by Cox *et al.* (US 5,034,189)★).

This rejection is maintained for reasons of record set forth in the Office Action mailed 06/29/06.

The Applicant argues that the composition of Nikiforov ('655) is formed in a fluorescence polarization and conditions required to form the Applicant's composition are absent in fluorescence polarization (Remarks, Pg. 7, Lines 18-20).

The Applicant argues that the composition of Nikiforov ('655) does not require the spatial arrangement and compound identity as in the Applicant's composition. The Applicant states that Nikiforov ('655) only teaches a large binding component containing a multivalent metal ion, and that use of a multivalent metal ion alone would not be sufficient to affect the fluorophore in a fluorescence polarization assay (Remarks, Pg. 7, Lines 19-25).

The argument is put forth that the Applicant's compositional arrangement is unique from that of the composition of Nikiforov ('655), the Applicant's composition being; a substrate containing the fluorophore and a target group which must have the paramagnetic metal ion bound to it, forming a complex of the target group and the paramagnetic metal ion in sufficient proximity to the fluorophore so that quenching can result when the complex forms (Remarks, Pg. 7, Lines 19-34).

The Applicant argues that similarly Nikiforov ('141) does not anticipate the Applicant's composition because Nikiforov ('141) also discloses a fluorescent polarization assay and further teaches a nonspecific interaction between the binding component and the fluorescent probe (Remarks, Pg. 8, Lines 3-8).

Response to Arguments

Applicant's arguments have been considered but are not found to be persuasive for the following reasons, the spatial arrangement of the composition of Nikiforov('655); a substrate containing a fluorescent label (fluorophore) and a phosphoryl group (target group), a binding component comprising multivalent metal ions which binds to the target group so as to cause a shift in the amount of polarized fluorescence emitted from the phosphorylated product when combined with the teachings of Cox *et al.* that multivalent (paramagnetic) metal ions possess quenching properties over fluorophores, is sufficient to infer that while quenching of fluorescence was not measured or even intended by the assay of Nikiforov ('655), that there is every reasonable expectation that quenching does occur. The argument that the conditions of the Nikiforov ('655) assay vs. the Applicant's assay are different because one measures a change in fluorescent polarization and the other and change in fluorescence emission is not persuasive because the means of measurement does not change the fact that the composition is the composition regardless of how the shift in fluorescence is finally measured.

The Applicant's argument regarding the teachings of Nikiforov ('141) is not found persuasive due to the above analysis with regards to Nikiforov ('655) above and because the composition of Nikiforov ('141) clearly interact (bind) in a specific manner (Column 14, Lines 40-54 and Figs. 3 and 4).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nikiforov (US 6,472,141 B2) as evidenced by Cox *et al.* (US 5,034,189)★) for reasons of record set forth in the prior Office Action filed 06/29/06.

Conclusion

No Claims are allowed, claims 14-22 appear to be free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

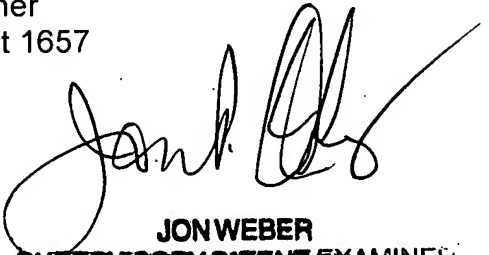
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/30/06

Paul Martin
Examiner
Art Unit 1657



JON WEBER
SUPERVISORY PATENT EXAMINER